



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2015-0276; FRL-9971-08]**

**Final Test Guidelines; Series 810 - Product Performance Test Guidelines; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is announcing the availability of the following 810 Series final test guidelines:

General Considerations for Testing Public Health Antimicrobial Pesticides – Guidance for Efficacy Testing, OCSPP Test Guideline 810.2000; Sterilants, Sporicides, and Decontaminants – Guidance for Efficacy Testing, OCSPP Test Guideline 810.2100; and Disinfectants for Use on Environmental Surfaces – Guidance for Efficacy Testing, OCSPP Test Guideline 810.2200. These test guidelines are part of a series of test guidelines established by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in testing pesticides and chemical substances. The test guidelines serve as a compendium of accepted scientific methodologies and protocols for testing that is intended to provide data to inform regulatory decisions. The test guidelines provide guidance for conducting the tests, and are also used by EPA, the public, and companies that are subject to data submission requirements under one or more statutes.

**FOR FURTHER INFORMATION CONTACT:** Thao Pham, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-308-0125; email address: [pham.thao@epa.gov](mailto:pham.thao@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

EPA is announcing the availability of three final test guidelines: General Considerations for Testing Public Health Antimicrobial Pesticides – Guidance for Efficacy Testing, OCSPP Test

Guideline 810.2000; Sterilants, Sporicides, and Decontaminants – Guidance for Efficacy Testing, OCSPP Test Guideline 810.2100; and Disinfectants for Use on Environmental Surfaces – Guidance for Efficacy Testing, OCSPP Test Guideline 810.2200.

These final test guidelines are part of a series of test guidelines established by OCSPP for use in testing pesticides and chemical substances to develop data for submission to the Agency under the Federal Food, Drug and Cosmetic (FFDCA) section 408 (21 U.S.C. 346a), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*). The test guidelines serve as a compendium of accepted scientific methodologies and protocols for testing that is intended to provide data to inform regulatory decisions under TSCA, FIFRA, and/or FFDCA.

The test guidelines provide guidance for conducting tests, and are also used by EPA, the public, and companies that are subject to data submission requirements under TSCA, FIFRA, and/or FFDCA. As guidance documents, the test guidelines are not binding on either EPA or any outside parties, and EPA may depart from the test guidelines where circumstances warrant and without prior notice. At places in this guidance, the Agency uses the word “should.” In this guidance, use of “should” with regard to an action means that the action is recommended rather than mandatory. The procedures contained in the test guidelines are recommended for generating the data that are the subject of the particular test guideline, but EPA recognizes that departures may be appropriate in specific situations. You may propose alternatives to the recommendations described in the test guidelines, and the Agency will assess them for appropriateness on a case-by-case basis.

## **II. General Information**

### ***A. Does this Action Apply to Me?***

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of pesticides and chemical substances for submission to EPA under TSCA, FIFRA, and/or FFDCA, the Agency has not attempted to describe all the specific entities that may be affected by this action.

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket for this document.* The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0276, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

2. *Electronic access to the OCSPP test guidelines.* To access OCSPP test guidelines electronically, please go to <http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm>. You may also access the test guidelines in <http://www.regulations.gov>, grouped by series under docket ID numbers: EPA-HQ-OPPT-2009-0150 through EPA-HQ-OPPT-2009-0159 and EPA-HQ-OPPT-2009-0576.

### **III. Overview**

*A. What Action is EPA Taking?*

EPA is announcing the availability of final test guidelines under Series 810, entitled “Product Performance Test Guidelines” and identified as OCSPP Test Guidelines 810.2000, 810.2100, and 810.2200. The OCSPP 810 Test Guideline Series addresses antimicrobial pesticide

products with public health uses or that bear public health claims for which product performance (efficacy) test data are required to be submitted to the Agency to support registration or amended registration, including, but not limited to the requirements of 40 CFR 158.2220(a)(2). These guidelines provide an update to the 2012 OCSPP Guidelines 810.2000, 810.2100, and 810.2200 and supersede previous efficacy testing guidance for sterilants, sporicides, decontaminants, and disinfectant products.

All studies initiated one year after the final publication date should utilize the revised guidelines for testing.

*B. How Was This Final Test Guideline Developed?*

The updated test guidelines integrate agency policies and revised test methods that have been released after the 2012 publication of the 810 guideline series. The availability of public draft test guidelines for public comment was announced in a June 17, 2015 **Federal Register** notice (80 FR 34638) (FRL-9927-37). The public draft test guidelines were placed in the EPA Docket for public access. These final test guidelines were reformatted for ease of navigation and reading and incorporate changes resulting from the public comments received in response to the 2015 public draft test guidelines. The Agency is also making available in the docket a Response to Comments document that summarizes changes to the 2015 draft guidelines and addresses issues raised in the public comment submissions.

**Authority:** 7 U.S.C. 136 *et seq.*; 15 U.S.C. 2601 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: February 6, 2018.

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